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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,421	09/15/2005	Jeremy S Melker	10457-064US	9466

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EXAMINER	
COLELLO, ERIN L	

ART UNIT	PAPER NUMBER
3734	

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05/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,421	MELKER, JEREMY S	
	Examiner	Art Unit	
	ERIN COLELLO	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *15 September 2005, 03 May 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-12 are pending.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the tubing with a first end affixed to the second probe and the second end affixed to the third probe must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by **Martinez (4,305,395).**

Regarding claim 1, Martinez discloses a probe (Figures 1, 2 and 3, (18)) useful in inserting a lacrimal stent comprising a proximal end and a distal end, said distal end being tapered to facilitate entry into a puncta of a patient (Column 3, Lines 39-41; Figure 3, (20))wherein said probe comprises a channel (Figure 2 see below) extending from said distal end to a sideport on said probe positioned between said proximal end and said distal end. (Figure 2, (24))

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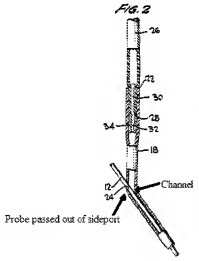


Regarding claim 2, Martinez discloses that the distal end is rigid. (Column 4, Lines 9, 20-23; wherein probe (18) overall is flexible, however in order for practical probe insertion the distal end would logically be rigid to prevent tearing during insertion.)

Regarding claim 3, Martinez discloses a probe (Figures 1, 2 and 3, (18)) useful in inserting a lacrimal stent comprising a proximal end and a distal end (Column 3, Lines 39-41); said distal end being flexible and comprising a blunt tip (Figure 3, (20); Column 4, Lines 20-23) wherein said probe comprises a channel (Figure 2 see above) extending from said distal end to a sideport on said probe positioned between said proximal end and said distal end. (Figure 2, (24))

Regarding claim 4, Martinez discloses that the proximal end is affixed thereto a lacrimal stent tube. (Figure 2, (26))

Regarding claim 5, Martinez discloses a kit (Column 3, Lines 8-10) comprising at least one first probe (Figures 1, 2, 3, (18)) comprising a proximal end and a distal end, said distal end channel being tapered to facilitate entry into a puncta of a patient (Column 3, Lines 39-41), wherein said at least one first probe (Figures 1, 2, 3, (18)) comprises a channel (Figure 2 see above) extending from said distal end to a sideport on said probe positioned between said proximal end and said distal end (Figure 2, (24)); and at least one second probe (Figures 1, 2, 3, (18)) comprising a proximal end and a distal end, said distal end being flexible and comprising a blunt tip (Figure 3, (20); Column 4, Lines 20-23) wherein said probe comprises a channel (Figure 2 see above) extending from said distal end to a sideport on said probe positioned between said proximal end and said distal end (Figure 2, (24)); whereby said first and second probes

are useful in assisting with insertion of lacrimal stents in a patient in need thereof (Column 3, Lines 39-41)

Regarding claim 6, Martinez discloses that at least one first probe comprises a rigid, tapered probe. (Column 4, Lines 9 and 20-23)

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

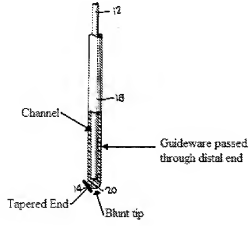
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Martinez (4,305,395)** in view and **Becker et al. (5,169,386)**.

Regarding claim 7, Martinez discloses a method for inserting a lacrimal stent comprising inserting a tapered probe into a puncta of a patient to dilate said punta to a desired opening size (Column 3, Lines 39-41); said tapered probe comprising a rigid distal end, a proximal end, and a channel (Figure 3 see below) extending from said distal end to a sideport between said distal end and said proximal end of said tapered probe (Figure 2, (24)); passing a guidewire (Figure 3, (12); Column 4, Line 15) comprising a distal end and a proximal end through said tapered probe such that said distal end of said guidewire is passed through said sideport (Figure 2 see above; Figure 3 see below) into said puncta, and positioned in the patient's lacrimal apparatus at a

desired depth (Column 4, Lines 60-67) and removing said tapered probe (Column 5, Lines 4-6).

FIG. 3



Martinez fails to disclose that the guidewire is passed out of the tapered probe.

However, Becker teaches a probe where the guidewire is passed out of the distal end of a tapered probe (Figure 2, (34); Column 7, Lines 19-20).

It would have been obvious at the time the invention was made to modify the probe so that the guidewire passes out of the end of the probe since such a modification allows the guidewire to remain in place after the probe is removed

Regarding claim 8, Martinez discloses the step of passing said guidewire through a second probe comprising a distal end, a proximal end (Column 4, Line 15; Figure 1, (12)), and a channel (Figure 2 see above) extending from said distal end to a sideport between said distal end and said proximal end of said second probe (Figure 2, (24)), such that said guidewire is passed through said distal end, through said channel

and out said sideport (Figure 2 see above; Figure 3 see above); and inserting said second probe into said puncta, wherein said second probe is guided into said patient's lacrimal apparatus at a desired depth (Column 4, Lines 60-67) and removing said guidewire from said patient. (Column 5, Lines 4-6)

Regarding claim 9, Martinez discloses that the distal end of said second probe is flexible and comprises a blunt tip. (Figure 3, (20); Column 4, Lines 20-23)

Regarding claim 10, Martinez discloses that the second probe comprises a silastic tubing affixed to its proximal end. (Column 4, Lines 44-46)

Regarding claim 11, Martinez discloses that the silastic tubing comprises a first end and a second end (Figure 1, (26); Column 4, Lines 44-46) and wherein said first end is affixed to said second probe and said second end is affixed to another probe (Figure 1, (26), (18)) comprising a distal end, a proximal end, and a channel extending from said distal end to a sideport between said distal end of probe. (Figure 2 see above)

Martinez fails to disclose that there are three probes.

However, Becker teaches that another probe may precede the insertion of the apparatus in order to allow the physician to determine the optimal insertion angle and proper maneuvering required. Therefore, the two probes of Martinez would be the second and third probes. (Figure 1, (10); Column 6, Lines 54-55, Column 7, Lines 1-4)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the kit of Martinez to include a first probe as taught by Becker since such a modification allows the physician to determine the optimal insertion

angle and proper maneuvering required before the probes carrying the stent are inserted.

Regarding claim 12, Martinez discloses that an upper puncta and a lower puncta (Figure 4, (36)); and wherein said second probe is inserted into said lacrimal apparatus through said lower puncta and the other probe is inserted into said lacrimal apparatus through said upper puncta. (Figure 5, (18))

Martinez fails to disclose a third probe.

However, Becker teaches that another probe may precede the insertion of the apparatus in order to allow the physician to determine the optimal insertion angle and proper maneuvering required. Therefore, the two probes of Martinez would be the second and third probes. (Figure 1, (10); Column 6, Lines 54-55, Column 7, Lines 1-4)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the kit of Martinez to include a first probe as taught by Becker since such a modification allows the physician to determine the optimal insertion angle and proper maneuvering required before the probes carrying the stent are inserted.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Kurihashi (US 6238,363 B1), Makino (EP 1 188 420 A1), Crawford (US 4,380,239), Walsh (US 6,547,765 B1), Herrick (US 6,149,684 A), and Lang (US 6,428,502 B1)**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIN COLELLO whose telephone number is (571)270-3212. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erin Colello/
Examiner, Art Unit 3734

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773